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Indian Standard

NEUROSURGICAL IMPLANTS — IMPLANTABLE PERIPHERAL NERVE STIMULATORS

ICS 11.040.40

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BUREAU OF INDIAN STANDARDS
MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG
NEW DELHI 110002

May 1999

Price Group 2

Neurosurgery Instruments Sectional Committee, MHD 7

FOREWORD

This Indian Standard was adopted by the Bureau of Indian Standards, after the draft finalized by the Neurosurgery Instruments Sectional Committee had been approved by the Medical Equipment and Hospital Planning Division Council.

The objective of this standard is to provide labelling requirements, certain safety and performance requirements, and reference test methods that will help establish a reasonable level of safety and effectiveness for implantable peripheral nerve stimulators intended for use in the relief of pain.

This standard reflects the conscientious efforts of those substantially concerned with its scope and provisions to develop a standard for those performance levels that could reasonably be achieved at this time.

This standard is based on the American National Standard ANSI/AAMI NS 15-1984 'Implantable peripheral nerve stimulators' issued by the American National Institute, Inc, New York.

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the results of a test, shall be rounded off in accordance with IS 2:1960 'Rules for rounding off numerical values (*revised*)'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

Indian Standard

NEUROSURGICAL IMPLANTS — IMPLANTABLE PERIPHERAL NERVE STIMULATORS

1 SCOPE

This standard establishes safety and performance requirements for implantable peripheral nerve stimulators intended for use in the relief of chronic, severe pain. The standard covers all elements of the peripheral nerve stimulation system, which consists of an implanted receiver, connected electrodes placed on or around the nerve, and an external transmitter for transmitting stimulating pulses across the patient's skin to the implanted receiver.

Transcutaneous electric nerve stimulators, spinal cord stimulators, totally implantable nerve stimulation system (that is, those with implantable pulse generators), and nerve stimulators intended for other applications, such as phrenic nerve diaphragm pacing are however not covered in this standard.

2 REFERENCE

The Indian Standard IS 13450 (Part 1) : 1994 'Medical electrical equipment: Part 1 General requirements for safety' contains provision which through reference in this text, constitutes provision of this standard. At the time of publication, the edition indicated above was valid. The standard is subject to revision and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent edition of the standard.

3 REQUIREMENTS

3.1 Labelling Requirements

In addition to the other statuary requirements, labelling on or accompanying implantable peripheral nerve stimulators shall comply with requirements of this section.

3.1.1 *Device Markings*

The device shall be labelled as an implantable peripheral nerve stimulator. The transmitter and receiver shall display the manufacturer's name, the model number, and the serial number.

3.1.2 *Information Manual/Package Insert*

A physician information manual or package insert and a patient information manual which may be combined with the physician manual shall be supplied with each device and shall contain at least the following:

a) A statement that the device is intended for use in the relief of chronic, severe pain;

b) A prescription legend as required by regulations;

c) Instructions for properly unpacking the unit so as to prevent physical damage and to retain the integrity of the sterile packaging (if applicable);

d) Instructions for implanting the receiver, including:
   1) Information about the proper method of placing the electrodes on or around the nerve;
   2) instructions for making the proper connections between the electrode leads and the receiver; and
   3) a warning, if applicable that the cuff electrode may cause compression of the nerve if it is too small;

e) Instructions for proper sterilization of the implantable components, or, if the device is supplied sterile by the manufacturer, the lot number, the date by which the device must be used, and a list of proper steps to be taken to ensure that sterility is not compromised;

f) Instructions for the assembly and operation of external components, including:
   1) A description of the function of the controls for voltage, pulse duration, pulse frequency, and other output parameters;
   2) A description of the means by which the battery can be tested;
   3) A description of how the antennae attach to the transmitter and of the proper placement of external components over the implanted receiver; and
   4) Instructions for testing the system to verify that it is functioning correctly;

g) Cautionary information, including:
   1) A statement that stimulation parameters must be determined under the supervision of a physician;
   2) A statement that stimulation at high outputs may cause unpleasant sensations or motor disturbances; and

  3) A statement that the stimulator should not be loaned to other individuals and that it should be kept out of the reach of children; and

h) Performance specifications, specifically the output currents and waveforms for all combinations of available dail settings for pulse width, frequency, and amplitude into a 500-ohm load.

3.1.3 *Registration*

The manufacturer shall provide means by which each implanted device can be registered with the manufacturer. A card to be returned to the manufacturer shall bear model number, and serial number of the device; it shall also provide space for the patient's name and hospital number, the name of the hospital, the date of implantation, the identification of the nerve stimulated, a description of the cause of pain and the name of the attending physician.

3.2 Performance Requirements

3.2.1 *Electrical Safety*

The risk current from the insulted wires shall not exceed 10 microamperes (µA) [*see also* IS 13450 (Part 1)].

3.2.2 *Stimulation Parameters*

The device shall be designed to produce at the electrodes a safe and effective current to stimulate the peripheral nerve. Although the best parameters for each patient cannot be predicted, the safe ranges of stimulation parameters have been determined in clinical trials, and the output of the device shall conform to the following parameter ranges:

a) Pulse Frequency : 1 to 100 Hertz (Hz);

b) Pulse Width : 50 to 2 000 microseconds (µs); and

c) Output Voltage/Current : 0 to 14 volts (V) through a 500-ohm (30 mA).

3.2.3 *Waveform*

The waveform shall consist of balanced positive and negative phases, so that the net charge through the electrodes is minimized.

3.2.4 *Controls*

Each device shall have an output-limiting control that can be set by the physician as clinical findings indicate. The output-limiting control shall be separate from the 'voltage' control used by the patient, so that the outputs set by the patient cannot exceed the maximum set by the physician.

3.2.5 *Dimensions of Cuff Electrodes*

For electrode systems designed to surround the nerve, the cuff diameter shall be at least one and a half times the diameter of the nerve to be stimulated [*see also* **3.1.2**(d)(3)].

3.2.6 *Materials*

The encapsulant and/or coating of the implanted receiver, the electrical insulation of the lead wires, the electrode pad, and the electrode shall be composed of materials shown to be biocompatible.

4 TESTS

This section provides referee test methods that shall be used to verify compliance of the device with the labelling and performance requirements.

4.1 Compliance with the Labelling Requirements

4.1.1 *Device Markings*

Compliance with the requirements of **3.1.1** shall be determined by visual inspection.

4.1.2 *Information Manual/Package Insert*

Compliance with the requirements of **3.1.2** shall be established by visual inspection, except for the electrical performance specifications required in **3.1.2** (h). The test circuit of Fig. 1 shall be used to measure the output characteristics to be reported and verified.

4.1.3 *Registration*

Compliance with the requirements of **3.1.3** shall be determined by visual inspection.

4.2 Compliance with the Performance Requirements

4.2.1 *Electrical Safety*

Test methods for establishing compliance shall be as given in IS 13450 (Part 1).

4.2.2 *Stimulation Parameters*

The test circuit for all parameter measurements shall consist of a simple, 500-ohm, resistive load, as shown in Fig. 1. The receiver output shall be tested at the maximum coupling efficiency achievable in the body (half-centimetre spacing between the transmitter antenna and the receiver).

a) Pulse Frequency or Repetition Rate (*PRR*) is measured as the reciprocal of the interval between two consecutive pulse onsets (*PI*), regardless of polarity [*see* Fig. 2(a)].

b) Pulse Width (*PW*) is measured at the midpoint of the pulse at the maximum pulse amplitude [*see* Fig. 2(b)].

c) Pulse Amplitude (*PA*) is measured, at a pulse width of 200 s, as the linear estimate of the average value of the pulse height from the start of the pulse onset 1 [*see* Fig 2(c)].

4.2.3 *Waveform*

The waveform shall be observed by means of the test circuit shown in Fig. 1. The receiver output capacitor should block the d.c. component of current into the load keeping 0 volt (V) level on the oscilloscope, at high enough sensitivity, the current distribution shall confirm the action of the blocking capacitor (*see* Fig. 3).

4.2.4 *Controls*

Compliance with the requirement of **3.2.4** shall be determined by visual inspection.

4.2.5 *Dimensions of Cuff Electrodes*

Compliance with the requirement of **3.2.5** shall be determined by visual inspection.

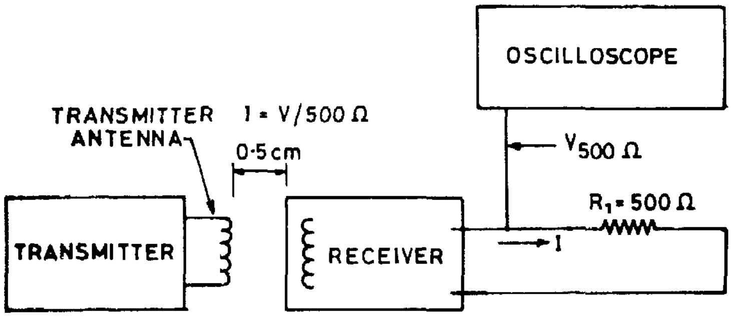

FIG. 1 TEST CIRCUIT FOR VERIFYING PERFORMANCE SPECIFICATIONS

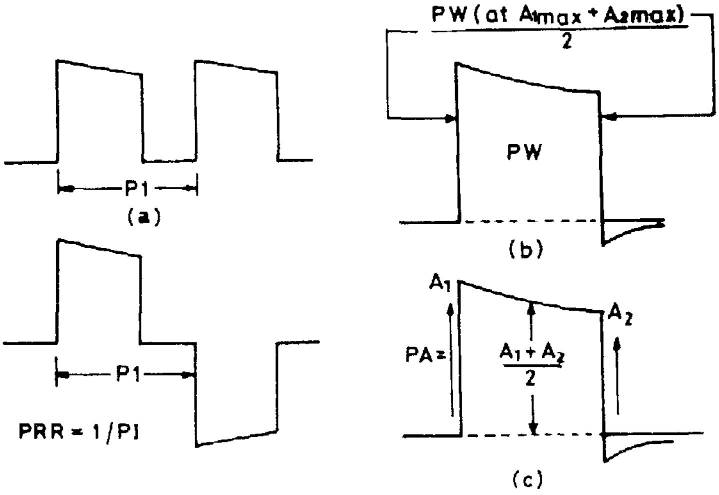

FIG. 2 MEASUREMENT OF PULSE REPETITION RATE (a), PULSE WIDTH (b), AND PULSE AMPLITUDE (c)

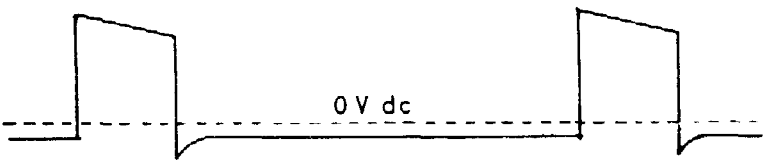

FIG. 3 CURRENT DISTRIBUTION AROUND 0 VOLT d.c.

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